DEPARTMENT OF HEALTH SERVICES
714/744 P STREET
P.O. BOX 942732
SACRAMENTO, CA 94234-7320

Application and Guidance For Approval of Alternative Medical Waste Treatment Technologies

The enclosed information has been assembled to provide guidance to applicants requesting approval of an Alternative Medical Waste Treatment Technology in California. These procedures apply to the approval process for treatment of medical waste in a manner other than by incineration, steam sterilization, or by approved discharge to a public sewer.

These guidelines comprise an interim document to be used while regulations are being promulgated by the Department pursuant to authorities in the Medical Waste Management Act. Interested parties will have ample opportunity to comment during the rule-making process.

APPLICATION FOR MEDICAL WASTE TREATMENT TECHNOLOGY APPROVAL

For an application to be deemed complete for review, submit this completed application form, an application developed per the attached guidance and a check in the amount of $2,500 made payable to the California Department of Health Services. All submittals should be mailed to:

Medical Waste Management Program
California Department of Health Services
P.O. Box 942732, MS 396
Sacramento, CA 94234-7320

Company Name _____

Applicant Name _____

Applicant Address _____

Applicant Telephone Number _____

Applicant Fax Number_____

Applicant E-mail address _____

For Department use only

Date Application package received _____

Date Check received by Department _____

Date review completed _____

Note: The review process will not commence until the complete application and fees have been received.

Criteria for Alternative Medical Waste Treatment Application

Provide complete information on the following topics related to the treatment process. Where information requested in this application is insufficient to adequately explain the process to the Department, please provide any additional information or data necessary to do so.

OPERATIONS

1. Briefly describe the technology in general terms–how it works; essential chemical or physical principles; scale of treatment.

2. Check all appropriate categories to best describe the methods used by the proposed technology. Check as many as necessary to fully describe the technology. If you check "other" please provide explanation.

Chemical	Oxidation	Mechanical	Shredder
	pH		Hammermill
	Other		Other
~~Heat~~ Thermal	Steam	Radiowave	
	Microwave	Plasma Arc	
Encasement		Other means of treatment (Attach description)	

3. Submit photographs and schematic drawings of the treatment system design.

4. Note the maximum amount of waste to be treated by this process per cycle and the length of the cycle.

5. Note any physical or chemical conditions which must be maintained in order to ensure the effectiveness of the treatment process.

6. Detail the consequences of these factors not being met.

7. Indicate compatible and non-compatible waste types for treatment using the proposed system. Below are examples of waste types.

Laboratory Waste (describe)	Human/animal specimen cultures
Cultures & Stocks of infectious agents	Wastes from the production of bacteria viruses, use of spores, discarded live and attenuated vaccines, culture dishes & associated devices
Human surgery or autopsy specimens	Animal parts, tissues, fluids, carcasses
Recognizable fluid blood, blood products, containers, or equipment containing blood	Excretions, exudates, secretions from humans or animals requiring isolation
Needles, syringes, pipettes, other contaminated broken glass or sharp objects	Recognizable human anatomical parts

8. Describe the technology's relative suitability for use at the waste's point of origin and/or at an off-site treatment facility as applicable.

9. For alternative treatment technology that depends on chemical disinfection include the following information.

- Name of the disinfectant and the active ingredient
- Concentration required to be used and maintained
- pH
- Contact time
- Recommended compatibility of specific materials and surfaces

10. Indicate the residual concentration of the disinfectant after it has been exposed to air and contaminated medical waste.

11. Note whether the disinfectant is classified as a hazardous waste under the Federal Resource Conservation and Recovery Act (RCRA) or the California Hazardous Waste Control Act. Is the treated medical waste so classified?

12. Describe any special training and/or knowledge necessary to operate the treatment system and how this information is provided to users of the technology.

HEALTH AND SAFETY

13. List acute and/or chronic health and/or safety hazards associated with any operation of the treatment technology.

14. List acute and/or chronic health and/or safety hazards associated with use of the chemicals used in the treatment technology.

MAINTENANCE

15. Describe maintenance required to operate the treatment system on an ongoing basis. Provide a projected downtime, as a proportion of operating time, necessary to complete these activities.

16. Provide the calibration schedule and/or protocol necessary to ensure that all treatment parameters are met.

QUALITY ASSURANCE/QUALITY CONTROL

17. Describe the quality assurance/quality control process used to determine that the waste has been properly and adequately treated. Include information regarding all applicable physical or chemical variables such as time, temperature, pH or pressure.

18. Also list, and describe the use of, any indicators, integrators or other monitoring devices that would be used for this purpose

19. Note the recommended frequency for their use.

ENVIRONMENTAL EFFECTS

20. Describe appropriate disposal options for wastes treated using this technology

21. Describe how byproducts will be disposed of and any environmental effects mitigated.

22. Indicate all byproducts that may be generated as a result of this alternative treatment technology. Use the listing as example byproducts.

Heat	Vapors	Fumes
Ash	Odor	Liquids (describe)
Slag	Air Emissions (describe)	Dust
Smoke	Steam	**Other**

23. Describe any effects on the environment anticipated from the disposal of waste treated using this alternative treatment technology.

24. Describe environmental, occupational or public health hazards associated with any potential malfunction of the treatment process or equipment. Include the emergency plan or operational protocol addressing these measures. Describe emergency measures required in the event of such a malfunction. Indicate any training and procedures provided to the users of the treatment technology to lessen the risk of these hazards.

25. If the treatment process includes the use of water, steam or other liquids, describe how liquid waste discharge is to be neutralized and removed (e.g. sewer, recycle, etc.).

TESTING AND OTHER REQUIREMENTS

26. Any proposed treatment method shall be capable of destroying pathogenic micro-organisms, including bacteria, fungi or yeasts, bacterial spores and viruses, as well as bacteria which are resistant to heat, antibiotics and disinfectants. The criteria include a 6 Log_{10} reduction in the concentration of a *Mycobacterium sp.* e.g., *M Terri*, *M. phlei,* or other species of mycobacteria, and a 4 Log_{10} reduction in the level of *Bacillus* spores. Other test organisms may be required if deemed necessary by the Department. Testing must provide data which demonstrate that the proposed technology achieves these criteria.

Prior to submittal of the applicant's data package, both the testing laboratory and the proposed testing protocol must be approved by the Department. An approved testing laboratory will be accredited by the Department's Laboratory Field Services Branch, or otherwise expressly approved by the Department. Protocols will meet the applicable guidelines set forth in Appendix A, "Elements of a Complete Report", attached. A universal protocol for testing of disinfecting coagulants which treat suction canister waste is available from the Department upon request.

27. Chemical disinfectants must also be properly registered with the United States Environmental Protection Agency (EPA). If not currently registered indicate the status of the application.

28. Chemical disinfectants must be properly registered with the California Environmental Protection Agency (Cal-EPA), Department of Pesticide Regulation, and Pesticide Registration Branch prior to use in California. Provide the DPR registration number, and include a sample product label in the application package. If not currently registered indicate the status of the application.

Process-Specific Testing Requirements

29. Some treatment modalities present unique challenges to proving efficacious treatment. The Department may require the use of specific or generalized protocols which may be included to this document by reference or as appendices. At present the following class(es) of treatment modalities may be tested *only* through use of such referenced protocols. (See appendix.)

- Chemical treatment/solidifiers for suction canister waste.

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APPENDIX A

Elements of a Complete Report

The following are elements expected in a complete final report of efficacy testing. Applicable portions of this appendix should also be used in preparing testing protocols for submittal.

- All documents must be provided to the Department directly from the testing laboratory. The applicant will be copied on all communications between the Department and the testing laboratory. However it will be necessary for direct communications between the Department and the laboratory.
- The protocol must be a complete description of all procedures from start to finish of the testing. The level of detail of reporting must be such that a qualified microbiology laboratory (such as the Department's Laboratory Central Services staff) with access to standard laboratory references would be able to replicate the study.
- The report must be a complete description of all procedures from start to finish of the testing as performed. The level of detail of reporting must be such that a qualified microbiology laboratory (such as the Department's Laboratory Central Services staff) with access to standard laboratory references would be able to replicate the study.
- QA/QC records must be made available on request.
- The report must contain a process flow diagram in sufficient detail to reflect all information presented in the procedure description.
- The report must be free of extraneous material. "Boilerplate" language that is not specifically germane to the specific tests performed must not be included. Data or procedures taken from sources other than the specific tests performed are not acceptable.
- Each step must be traceable to standard reference works, or to protocols expressly approved as reference protocols by the department.
- "In house" procedures must be
  1. Justified as to their necessity,
  2. Verified, if quantitative, as to validity and reliability of the procedure, and
  3. Approved by the Department.
- Source of all organisms must be cited.
- All procedures used in growing cultures including any applicable test inocula must be described
- All data must be available on request by the Department.
- The report must include at a minimum, summary processed data and graphs and sufficient information to confirm the conclusions found by the summary data.
- Results must be able to be substantiated by all supporting raw data

(end)